K122416

Artiglass S.r.l.

MAY 0 3 2013

Artiglass L.O.R. Glass Syringe
510 (k) Summary

Submitted by:

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Date of submission: April 29, 2013

Device name:

Trade name:	Artiglass L.O.R. Glass Syringes
Common name:	Syringe, Piston
Classification:	Class II, 21 CFR 880.5860
Product Code:	FMF

Predicate device:

Trade name:	Spectra, LOR GLASS SYRINGE
Manufacturer:	Spectra Medical device, Inc.
510(K) Number:	K082674

Description of the device:

Artiglass L.O.R. Glass Syringe is glass syringe similar to that of a standard piston syringe. It is intended for use in conjunction with an epidural needle, to verify the needle tip placement in the epidural space by the Loss of Resistance technique.
The Artiglass L.O.R. Glass Syringe is provided not sterile, in bulk form to other manufacturers as part of an epidural insertion trays as a component to the epidural kit. The syringe may be sterilized before use and it can be re-sterilized via Autoclave.
Artiglass L.O.R. Glass Syringe is intended to be used only by qualified personnel. This syringe is not intended for injection or aspiration.
The Artiglass L.O.R. Glass Syringe is available in volume of 5ml and 10 ml.

Intended Use:

The Artiglass LOR Glass Syringe is intended for use, in conjunction with an epidural needle, to verify the needle tip placement in the epidural space by the Loss of Resistance technique as explained in standard medical textbooks. These syringes are not intended for injection or aspiration.

Performance Testing:

Design Verification tests were performed based on the risk analysis and product requirements.
Results of the tests demonstrates that the Artiglass L.O.R. Glass Syringe performs in same modality of the predicate device and that it is safe and effective when used as intended.

Design Verification tests for Artiglass L.O.R. Glass Syringes performance elements include:

Item#	Performance Specification	Status of Artiglass L.O.R. Glass Syringes
1	ISO 594/1 Conical fitting with a 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 1: General requirements	Complying
2	ISO 595/1 Reusable all-glass or metal-and-glass syringes for medical use – Part 1: Dimensions	Complying
3	ISO 594-2 Second edition 1998-09-01 Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 2: Lock fittings	Complying
4	ISO 595-2 First Edition 1987-12-15 Reusable all-glass or metal-and-glass syringes for medical use – Part 2: Design, performance requirements tests	Complying

Performance testing including bench and animal testing was conducted to assess the safety and effectiveness of the Artiglass L.O.R. Glass Syringes for the stated indications for use. Results of performance testing demonstrated that the Artiglass L.O.R. Glass Syringes is safe and effective in the proposed intended uses.

Technological characteristics:

As compared to the predicate device, the Artiglass L.O.R. Glass Syringe object of this 510(k) submission:

a) Operates under the same operating principle as the predicate device.
b) Is similar in dimension and component characteristics to the predicate device.
c) Has similar glass luer tip and metal luer tip of the predicate device.
d) Has a similar luer lock connector as the predicate device.
e) Is supplied not sterile as the predicate device.
f) Meets the requirements of ISO 594/1 and 594/2.
g) Meets the requirements of ISO 595/1 and 595/2.
h) Meets the requirements of ISO 14971:2009, as applicable to the intended use of the device.
i) Meets the requirements of ISO 10993 as applicable to the intended use, description and technological characteristics of the device.
j) Demonstrates equivalent performance to the predicate device during design verification testing.

Conclusion:

The conclusions drawn from the actual conducted (as well as the referenced) analytical engineering evaluations, the non-clinical tests and the commercial use of similar predicate device demonstrate that Artiglass L.O.R. Glass Syringes are safe and effective and that it performs at least as safely and effectively as the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 3, 2013

Mr. Federico Baccarin
Managing Director
ArtiGlass S.r.l.
Via Piemonte 13
Due Carrare Padova
Italy 35020

Re: K122416
Trade/Device Name: Artiglass L.O.R. Glass Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: April 10, 2013
Received: April 15, 2013

Dear Mr. Baccarin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K122416**

Device Name: Artiglass L.O.R. Glass Syringes

Indications for Use: The Artiglass LOR Glass Syringe is intended for use, in conjunction with an epidural needle, to verify the needle tip placement in the epidural space by the Loss of Resistance technique as explained in standard medical textbooks. These syringes are not intended for injection or aspiration.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Richard C. Chapman
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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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